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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,957	01/30/2004	Ian MacMillan Ward	604-708	2507

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EXAMINER
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DIXON, MERRICK L

ART UNIT	PAPER NUMBER
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1774

DATE MAILED: 02/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/766,957

Applicant(s)

WARD ET AL

Examiner

Merrick Dixon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date see office action.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

  
MERRICK DIXON  
PRIMARY EXAMINER

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1. The abstract of the disclosure is objected to because it contains the legal word "comprising". Correction is required. See MPEP § 608.01(b).

The instant office action contains an initialed, signed copy of a PTO-1449 with date 1-30-2004.

2. Claims 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites a Markush group. Related corrections are requested.

In claims 59-60, applicants has recited both process and article limitations in the alternative in each respective claim. Applicants must claim one or the other. Such alternate recitation is forbidden.

Concerning claims 59-60, The examiner will address the limitations relating to the composite hereinbelow.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 1-6,9-18,22-25 and 59-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Turner( US 4662887).

The cited reference teaches the claimed invention comprising a composite comprising an inorganic filler material and orientated fibrous polymeric material fused together- col 3, lines 54- col 4, line 4. Concerning claims 2 and 3, the reference teaches chopped fibers in col 3, lines 65-68, example 2 and void free composite material in col 3, lines 8-22; col 3, 35-52 . Concerning claims 4 and 5, the reference teaches similar filler material in col 1, lines 35-50. Concerning claim 6, the reference teaches biocompatible material in col 4, lines 15-17. Concerning claims 11-18, the reference teaches similar modulus in its Examples 1-5. Concerning claim 61, the reference teaches prosthesis in the abstract. Concerning claims 22-24, the reference teaches such high modulus material, including polyethylene in col 3, lines 16-23. Concerning claim 25, the reference teaches such claimed recrystallized melt phrase in col 4, lines 25-29. Concerning claims 59-60, the reference teaches the claimed composite as articulated above and finally, concerning claims 9 and 10, the reference teaches well known claimed method such as extrusion in col 3, lines 65-67.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. Claims 19-21 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Turner (US 4662887).

Turner anticipates all claims which claims 19-21 depend from. Therefore, it is submitted, such claimed ductility would have been inherent.

In the alternative, because Turner teaches all the limitations from which such claims 19-21 depends, it is submitted the composite would indeed also possess, if not inherent, the claimed flexural ductilities, in the absence of unexpected result.

7. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turner(US 4662887) in view of Dorman (US 4842604).

Although the primary reference teaches biocompatible material in its composite ( col 4, lines 15-17), it fails to expressly teach hydroxyapatite and apatite biocompatible material. The secondary reference, however, teaches that it is known in the art to use such material in prosthetic products- col 5, lines 30-38. It would have been obvious to one of ordinary skill in the art at the time the invention is made to combine the teachings of the secondary reference to Dorman and utilize such material in the primary reference's prosthetic product in an attempt to promote bone growth in the host wearer- col 1, lines 23-35.

8. Claims 55-58 rejected under 35 U.S.C. 103(a) as being unpatentable over Turner(US 4662887) in view of Bonfield et al(US 5017627). The primary reference to

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Turner was discussed above, inter alia. The reference fails to teach its polymer material being homo or copolymer material. The secondary reference to Bonfield et al, however, teaches that it is known in the instant art to utilize such claimed polymeric material in orthopaedic devices as taught by the primary reference- col 1, lines 55-60. it would have been obvious to one of ordinary skill in the art at the time the invention is made to combine the teachings of the reference to Bonfield and utilize such well known polymeric material, as copolymer or homo polymer of a polyolefin , in the primary reference in the absence of unexpected results and for further reasons to impart desired properties thereto. Concerning claims 56-58, the secondary reference teaches similarly claimed molecular weights – col 1, line 66- col 2, line 6.

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6017834 in view of Bonfield et al(US 5017627). US Patent 6017834, fails to teach inorganic filler

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material in its composite. The secondary reference , however, teaches that it is notoriously well known in the art to include inorganic filler material in prosthetic devices- col 1, line 53- col 2, line 12. It is submitted that such inclusions taught by the secondary reference, would have resulted in the claimed invention, in the absence of unexpected results.

11. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

12. Claims 26 and 29 rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6017834. This is a double patenting rejection.

13. Claims 26-28, 31,32,34-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Bonfield et al(US5017627).

The cited reference teaches the claimed process including mixing polymeric material with filler material, maintaining pressure to same, heating same and compressing the heated combined material- col 2, lines 34-59; see reference. Concerning claim 27, the reference teaches mixing step in col 2, lines 55-58. Concerning claims 41-45, the

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reference teaches extruding its material during its patented process in col 2, lines 53-56. Concerning claim 51, it is submitted the particular type fluid used in the extrusion machine is of no patentable consequences to the instant question for patentability which must be manipulatively distinct. However, it is submitted that it is notoriously well known in the art to utilize such oil material in the cited reference's device to prolong the device useful life.

Similarly and concerning claims 46 and 47, the particular device used during the claimed process must affect the process in a manipulative way- Ex parte Pfeiffer, 1962 C.D. 408 (1961). Thus the cited device limitations are not given patentable weight.

Concerning claims 34,35, 39 and 40, the reference teaches the aspect of maintaining a temperature point during the patented process- col 2, lines 38-41.

Concerning claims 48-50, the claimed resulting extrusion ratio depends on the device used during the claimed process. Accordingly and as discussed above, such device is not given patentable weight in the instant question for patentability. Concerning claims 31 and 32, directed to article limitations, the limitations are directed to article limitations and are believed of no patentable consequences to the instant question for patentability which must be manipulatively distinct.

14. Claims 28-32 and 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turner et al(US4662887) in view of Dorman et al (US 4842604). The turner patent was discussed above. It discloses the basic claimed process. Although Turner applies pressure to its composite material while forming same (i.e. during



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extrusion and molding ) col 3, lines 58- col 4, line 4, the secondary reference to Dorman et al more clearly shows this aspect- Example 11. the secondary reference teaches applying various pressures to the composite, including contact and compaction pressures- col 10, lines 8-31. It would have been obvious to one of ordinary skill in the art at the time the invention is made to manipulate the primary reference into various and desired shapes/forms via specific pressure manipulations on same. Concerning claims 31 and 32, the claimed percentage weight of the fibers in the composite, is directed to article limitations and is of no patentable consequences to the instant question for patentable which much be manipulatively distinct – Ex parte Pfeiffer, 1962 C.D. 408(1961). Concerning claims 52-54, the secondary reference teaches various amounts of pressure being applied to the composite during its formation- see above. It is submitted that obtaining the optimum value of such a result effective variable involves only routine skill in the art and would have been obtained in the cited reference- In re Boesch, 617 F.2d 272,205 USPQ 215(CCPA 1980).

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Applicants who wish to send a facsimile (draft copies) for the examiner's immediate review can do so by using the Examiner's personal fax number at 571-273-1520. The faxing of all papers must conform with the notice published in the Official Gazette, 1096 O.G. 30 ( November 15, 1989). **NOTE: All facsimiles sent to the examiner's personal fax number should be in draft-forms and will be treated as informal.**

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**Same facsimiles will not be entered in the related applications unless**

**otherwise agreed and noted by the examiner.**

**The fax number for all other fascimile is 703-872-9306.**

Information about **the status of an application** may be obtained from the Patent

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or **Public PAIR**. Questions about the PAIR system should be directed to the Electronic

Business Center at **866-217-9197**.

Any questions concerning the instant communication should be directed to Examiner

Dixon, at 571-272-1520, Mondays to Thursdays, between 12 noon and 8 PM, eastern

time . The examiner's supervisor, Mrs. Rena Dye, can be reached at 571-272-3186.



Merrick Dixon

Primary Examiner

Group 1700